



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carl-Axel Bauer *et al.* Art Unit : 1617
Serial No. : 10/010,283 Examiner : Jennifer M. Kim
Filed : November 13, 2001
Title : NEW USE FOR BUDESONIDE AND FORMOTEROL

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO ACTION OF JUNE 18, 2004

In reply to the Office Action of June 18, 2004, Applicants submit the following remarks. ✓

Claims 9 and 11-25 are pending in the application. The references *Nederland Tijdschrift Voor Geneeskunde* and *Saunders Manual of Medical Practice* have been withdrawn with respect to the obviousness rejection.

Claims 9 and 11-25 were rejected under 37 C.F.R. §103(a) as being unpatentable over *Carling et al.*, of record, in view of *Cazzola et al.* (U) of record and *Andersson et al.* (U.S. Patent No. 6,598,603 B1) and further in view of *Giardina et al.* (U.S. Patent No. 6,277,862 B1). The Examiner alleges that while *Carling et al.* do not expressly teach the treatment of COPD, *Cazzola et al.* teach that formoterol is effective in patients with COPD, *Andersson et al.* teach that budesonide is useful for “treating COPD as well as asthma” (page 3 of the Office Action), and *Giardina et al.* report that COPD and asthma are respiratory disorders. The Examiner concludes that “[a]bsent any evidence to the contrary, there would have been a reasonable expectation of successfully treating COPD by employing Carling’s formulation to achieve greater efficiency and duration of action...” (page 4 of the Office Action).

Applicants respectfully traverse this rejection. Applicants will address, in turn, the Examiner’s contentions that (I) “it would have been obvious to ... employ the Carling medicament in treatment of COPD since COPD is well known respiratory disease as disclosed

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